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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,546

08/07/2006

Akihito Kamei

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8270

53080 7590 10/28/2009  
MCDERMOTT WILL & EMERY LLP  
600 13TH STREET, NW  
WASHINGTON, DC 20005-3096

EXAMINER

TURK, NEIL N

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

10/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/588,546	KAMEI ET AL.	
	Examiner	Art Unit	
	NEIL TURK	1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,5 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/25/07, 8/7/06</u> .                                         | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1 and 5** recite the limitation "the electric charge" with respect to the surface of the particles and the specific binding substance. Further, claims 1 and 5 recite "the same polarity". There is insufficient antecedent basis for these limitations in the claim.

**Claim 12** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recited openings of the liquid supply inlet are indefinitely recited as claim 5 does not establish that the liquid supply inlet includes an inner and an outer opening.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 4, 5, and 9-15** rejected under 35 U.S.C. 102(b) as being anticipated by Kawamura (EP 1359404).

Kawamura discloses a solution density measuring method and apparatus (abstract). Kawamura discloses a test liquid and reagent provided in a cell, in which stirring is caused by injection of the reagent into the test liquid (test liquid particles thereby being coated by the reagent for dissolving therein). Kawamura discloses that examples of the test liquid include blood (red blood cells being the plurality of particles), and test substances include albumin, hemoglobin, various hormones, and the like, and discloses that an appropriate reagent may be chosen for the given test liquid, including antibodies that are specifically bonded to respective test substances (par. [0025-0028], fig. 1). With regards to claim 10, Examiner asserts that the Rh or ABO antigens inherent to blood cells are a substance carried by the red blood cells that are capable of inhibiting the albumin antibody from adsorbing to the red blood cells. With regards to claim 11, Examiner asserts that the red blood cells carry proteins known as ion channels that regulate the flow of ions across the membrane in all cells, thereby providing a substance that adsorbs a substance (ions) that is capable of inhibiting the reaction between the albumin and the albumin antibody. Kawamura discloses a sample cell 1 (Examiner asserts that such a cell is held by the supporting surface on which the cell is placed) having an opening oriented upwardly, and two opposite sides are fitted with glass plates so as to act as optical windows (entrance/exit) corresponding to opposite ends of an optical path through which a parallel light 4 passes (originating from light source 3). Kawamura discloses that the light having passed through the test liquid is detected by a photosensor 5, a pump 6 injects the reagent liquid into the test liquid

from injection port 2, and a computer 7 analyzes the output signal of the photosensor 5 and controls pump 6 (par. [0029-0033], fig. 1&2; example of operation [0035-0043]).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawamura in view of Smith et al. (US 2003/0170145), hereafter Smith.

Kawamura has been discussed above.

Kawamura does not disclose that the liquid sample retaining section has a buffer.

Smith discloses a flow immunoassay assembly in which a buffer supply is included that provides buffer to the reaction chamber, and in the reaction chamber the buffer mixes with the test sample so as to not cause sudden changes during the immunoassay test that could cause the antibody to falsely release bound antigen in the absence of the analyte ([0022,0301]).

It would have been obvious to include a buffer in the retaining section of Kawamura such as taught by Smith in order to provide to control the pH of the test solution being assayed so as to not cause sudden changes during the immunoassay that could cause the antibody to falsely release bound antigen in the absence of the analyte.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797